

CHAPTER 7

SECTION 16.1

UNPROVEN DEVICES, MEDICAL TREATMENT, AND PROCEDURES

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I. POLICY

A. TRICARE/CHAMPUS regulations and program policies restrict benefits to those devices, treatments, or procedures for which the safety and efficacy have been proven to be comparable or superior to conventional therapies. Any device, medical treatment, or procedure whose safety and efficacy has not been established is unproven. Services and supplies considered to be unproven are excluded from coverage.

B. This exclusion includes all services directly related to the unproven device, medical treatment, or procedure.

C. Cost-sharing may be allowed for services or supplies when there is no logical or causal relationship between the unproven device, treatment, or procedure and the treatment at issue or where such a logical or causal relationship cannot be established with a sufficient degree of certainty. This cost-sharing is authorized in the following circumstances:

1. Treatment that is not related to the unproven device, treatment, or procedure; e.g., medically necessary treatment the beneficiary would have received in the absence of the unproven device, treatment, or procedure.

2. Treatment which is a necessary follow-up to the unproven device, treatment, or procedure, but which might have been necessary in the absence of the unproven treatment.

D. In making a determination that a device, medical treatment, or procedure has moved from the status of unproven to the position of nationally accepted medical practice, TMA uses the following hierarchy of reliable evidence:

1. Well controlled studies of clinically meaningful endpoints, published in refereed medical literature.

2. Published formal technology assessments.

3. The published reports of national professional medical associations.

4. Published national medical policy organization positions.

5. The published reports of national expert opinion organizations.

E. With respect to clinical studies, only those reports and articles containing scientifically valid data and published in the refereed medical and scientific literature shall be considered as meeting the requirements of reliable evidence. Specifically not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence or personal professional opinions. Also not included is the fact that a provider or a number of providers have elected to adopt a device, medical treatment or procedure as their personal treatment or procedure of choice or standard of practice.

F. TRICARE Policy and benefit structure are never based solely on coverage offered by other third party payers, including Medicare, since each operates under different rules and requirements.

G. The following is a partial list of devices, medical treatments, and procedures considered to be unproven. These are excluded from benefits. The list is not all inclusive. Other unproven devices, medical treatments, and procedures are similarly excluded, although they do not appear on this partial list. The codes listed have been associated with the respective unproven device, medical treatment, or procedure but may also be used for other applications which are not unproven. The listing of the procedure codes is for contractors to use in screening for unproven as opposed to proven application. The date listed with each device, medical treatment, or procedure indicates the date TRICARE Management Activity (TMA) reviewed the most recent literature to determine whether the device medical treatment, or procedure should remain on the unproven list. This partial list will be reviewed and updated periodically as new information becomes available. With respect to any device, medical treatment or procedure included on this partial list, if and when TMA determines that based on reliable evidence such device, medical treatment or procedure has proven medical effectiveness, TMA will initiate action to remove the device, medical treatment or procedure from this partial list of unproven devices, medical treatments or procedures. From the date established by TMA as the date the device, medical treatment or procedure has established proven medical effectiveness until the date the regulatory change is made to remove the device, medical treatment or procedure from the partial list, TMA will suspend treatment of the device, medical treatment or procedure as unproven. Following is the partial list of unproven devices, medical treatments or procedures, all of which are excluded from benefits:

1. Adoptive immunotherapy involving the harvesting and infusion of tumor infiltrating lymphocytes (TIL) for the treatment of cancer. December 1997.
2. Adrenal-to-brain transplantation for Parkinson's disease. January 1997.
3. Allogeneic bone marrow transplantation for:
 - a. Neuroblastoma. March 1997.
 - b. Waldenstrom's macroglobulinemia. May 1997.
 - c. Multiple Myeloma. April 1998.

d. Hodgkin's disease. May 1998.

4. Allogeneic donor bone marrow transplantation (infusion) performed with or after organ transplants for the purpose of increasing tolerance of the organ transplant. December 1996.

5. Allogeneic peripheral stem cell transplantation for non-Hodgkin's lymphoma. January 1997.

6. Ambulatory blood pressure monitoring. CPT codes are 93784 - 93790. February 1997.

7. Amniocentesis performed for ISO immunization to the ABO blood antigens. June 1996.

8. Applied kinesiology (purports to diagnose nutritional deficiencies by finding sensitive places on the body). January 1997.

9. Autologous umbilical cord blood transplantation therapy. March 1997.

10. Autolymphocyte therapy (ALT) (immunotherapy used for treating metastatic kidney cancer patients). December 1998.

11. Balloon dilatation of the prostate (CPT 52510). June 1996.

12. Biliopancreatic bypass for treatment of morbid obesity. January 1991.

13. Biofeedback for hypertension. June 1997.

14. Bladder stimulators to induce development of, or increase bladder continence, and to induce emptying the bladder. May 1998.

15. Brain electrical activity mapping (BEAM). January 1997.

16. Bullectomy for lung volume reduction. December 1998.

17. Calcium EAP/calcium orotate and selenium (also known as Nieper therapy) - Involves inpatient care and use of calcium compounds and other non-FDA approved drugs and special diets. Used for cancer, heart disease, diabetes, multiple sclerosis -- Not a proven treatment for any indication. December 1998.

18. Services related to the candidiasis hypersensitivity syndrome, yeast syndrome, or gastrointestinal candidiasis are unproven (i.e., allergenic extracts of *Candida albicans* for immunotherapy and/or provocation/neutralization). Disseminated systemic candidiasis (ICD-9-CM 112.5) is a recognized diagnosis, and medically necessary treatment is covered. December 5, 1996.

19. Cardiomyoplasty (Cardiac Wrap) for treatment of heart failure. December 1998.

20. Carotid Body Resection, both unilateral and bilateral, when done solely to relieve the symptoms of pulmonary dyspnea, including chronic obstructive pulmonary disease, is considered unproven. October 1996.

21. Cellular therapy. June 1996.

22. Cerebellar stimulators/pacemakers for the treatment of neurologic disorders. October 1996.

23. Cervicography. While it shows promise as a screening procedure when used in conjunction with the pap smear, additional studies are needed before it's considered beyond the unproven state.

24. Chelation therapy, except when using FDA-approved chelators for FDA-approved indications. August 1998.

25. Treatment of chronic fatigue syndrome. July 1996.

26. Cognitive rehabilitation services that are prescribed specifically and uniquely to teach compensatory methods to accomplish tasks which rely upon cognitive processes.

27. Computer-assisted Pap tests (AutoPap®, PAPNET®) for primary screening of Pap smear slides. January 1997.

28. Cryosurgery for prostate metastases. November 1996.

29. Diaphanography (Transillumination Light Scanning).

30. Donor lymphocyte infusion (donor buffy coat infusion, donor leukocyte infusion, donor mononuclear infusion) except for treatment of patients with CML who relapse following HDC with allogeneic BMT. June 1998.

31. Dorsal column and deep brain electrical stimulation for treatment of motor function disorders. December 1998.

32. Dorsal root entry zone (DREZ) thermocoagulation or microcoagulation neurosurgical procedure. August 1996.

33. Dynamic Posturography (both static and computerized). July 1996.

34. Electrostimulation of salivary production in the treatment of xerostomia secondary to Sjogren's syndrome. October 1996.

35. Endoscopic third ventriculostomy. June 1996.

36. Epidural steroid injections for thoracic pain. November 1997.

37. Epikeratophakia for treatment of aphakia and myopia. August 1996.

38. Estradiol pellet implants. Estradiol pellets are not FDA approved for general use in humans. July 1996.

39. Extracorporeal immunoadsorption using Protein A Columns is investigational in the treatment of disease process other than idiopathic thrombocytopenic purpura (ITP). June 1996.

40. Extraoperative electrocorticography for stimulation and recording in order to determine electrical thresholds of neurons as an indicator of seizure focus. December 1998.

41. Eye movement desensitization reprocessing therapy for treatment of anxiety-related disorders. December 1998.

42. Fetal tissue transplantation for movement disorders (including Parkinson's disease). July 1996.

43. Gait Analysis (also know as a walk study or electrodynogram). May 1995.

44. Gastric bubble or balloon. July 1996.

45. Gastric wrapping/gastric banding. October 1996.

46. Growth factor, including platelet-derived growth factors, for treating non-healing wounds. This includes Procuren®, a platelet-derived wound-healing formula. January 1997.

47. Hair analysis to identify mineral deficiencies from the chemical composition of hair is unproven. Hair analysis testing may be reimbursed when necessary to determine lead poisoning. January 1997.

48. Helium ion beam radiosurgery/radiotherapy for arteriovenous malformations and ependymoma. May 1997.

49. High dose chemotherapy with stem cell rescue (HDC/SCR) for any of the following malignancies:

- a. Ovarian cancer. October 1998.
- b. Testicular cancer. July 1996.
- c. Desmoplastic small round-cell tumor. May 1997.
- d. Non-metastatic breast cancer. October 1998.
- e. Yolk sac tumor (endodermal sinus tumor). November 1997.
- f. Cold agglutinin disease. December 1997.

50. Histamine therapy. June 1996.

51. Holding therapy - Involves holding the patient in an attempt to achieve interpersonal contact, and to improve the patient's ability to concentrate on learning tasks. December 1998.

52. Home uterine activity monitoring for the purpose of preventing pre-term labor and/or delivery. February 1997.

53. Human papillomavirus DNA testing in the management of cervical neoplasia. October 1995.

54. Hyperbaric oxygen therapy for treatment or complications of peripheral vascular disease. October 1996.

55. Hyperosmolar blood-brain barrier disruption produced by infusion of Mannitol to increase drug delivery to brain tumors. August 1998.

56. Hyperventilation Provocation Test (HVPT) for diagnosing hyperventilation syndrome. February 1997.

57. Immunotherapy for malignant disease except when using drugs approved by the FDA for this purpose. July 1996.

58. Implantable infusion pumps, except for treatment of spasticity, chronic intractable pain, and hepatic artery perfusion chemotherapy for the treatment of primary liver cancer or metastatic colorectal liver cancer. August 1996.

59. In utero fetal surgery. June 1996.

60. Intracavitary administration of cisplatin for malignant disease. July 1996.

61. Intraoperative monitoring of sensory evoked potentials (SEP) to define conceptional or gestational age in pre-term infants. October 1996.

62. Intraoperative Radiation Therapy. April 1996.

63. Iridology (links flaws in eye coloration with diseases elsewhere in the body). January 1997.

64. Keratomileusis. March 1997.

65. Ketogenic Diet. (Monitoring of the Ketogenic diet may be cost-shared when there is an otherwise covered medically necessary treatment for epilepsy).

66. Ligament replacement with absorbable copolymer carbon fiber scaffold. July 1996.

67. Light therapy for Seasonal Depression (also known as seasonal affective disorder (SAD)). - This therapy uses varying degrees of light to treat depression. July 1996.

68. Lung volume reduction therapy for any indication. May 1999.

69. Magnetic Resonance Angiography for indications other than those specifically listed as covered in the TRICARE/CHAMPUS Policy Manual. October 1995.

70. Meniscal transplant (allograft) for meniscal injury. July 1998.

71. Muscle resection for severe Parkinsonian tremor, intention tremor, or dystonia.

72. Myofunctional or tongue thrust therapy.

73. Navelbine®. Unlabeled use for refractory platinum-resistant epithelial ovarian cancer. May 1, 1996.

74. Neurofeedback. February 1998.

75. Neuromuscular electrical stimulation for the treatment of denervated muscles. March 1997.

76. All organ transplants not listed as covered in the TRICARE/CHAMPUS Policy Manual or [32 CFR 199.4\(e\)\(5\)](#). February 1998.

77. Orthoptics, also known as eye exercises, eye therapy, training, vision therapy, vision training. January 1996.

NOTE: Orthoptics are excluded by [32 CFR 199.4\(g\)\(46\)](#).

78. Percutaneous interstitial thermal ablation in the treatment of hepatic cancer. May 1998.

79. Percutaneous Transluminal Angioplasty (PTA) in the treatment of obstructive lesions of the carotid, vertebral and cerebral arteries. October 1996.

80. Peri-urethral Teflon injections to manage urinary incontinence.

81. Photopheresis for indications other than for treatment of skin manifestations of cutaneous T-cell lymphoma (CTCL) in persons who have not been responsive to other forms of treatment. May 1998.

82. Photorefractive keratectomy. March 1997.

83. Portable nocturnal hypoglycemia detectors. August 1996.

84. Positron emission tomography (PET) for diagnosis of intracranial masses, differentiation of low-grade and high-grade brain tumors, guidance of biopsy of intracranial mass, differentiation of brain tumor from radionecrosis, monitoring of response of treatment of brain tumors, and assessment of cerebrovascular disease. July 1996.

85. Prolotherapy, joint sclerotherapy, and ligamentous injections with sclerosing agents. June 1996.

86. Proton beam Radiosurgery/Radiotherapy for ependymoma and high grade glioma (glioblastoma multiforme). July 1998.
87. Pulmonary rehabilitation, except for pre- and post-lung and heart-lung transplant patients. September 1996.
88. Pupillometry. August 1995.
89. Radial keratotomy (refractive keratoplasty). (CPT 65771.) March 1997.
90. Radioimmunoguided surgery in the detection of cancer. November 1996.
91. Rhizotomy for Parkinsonian tremor, intention tremor, or dystonia.
92. Selective peripheral denervation for severe Parkinsonian tremor, intention tremor, or dystonia.
93. Sensory afferent stimulation (SAS) devices for relief of nausea (e.g., Relief Band®). August 1996.
94. Sensory evoked potentials (SEP) monitoring of the sciatic nerve during total hip replacement. SEP for monitoring simple laminectomies or other spinal procedures which are not considered to be a significant risk to the spinal cord. Recording SEPs in unconscious head injured patients to assess the status of the somatosensory system. The use of SEPs to define conceptional or gestational age in pre-term infants. April 1997.
95. Signal-Averaged ECG. June 1998.
96. Single photon emission computed tomography (SPECT) for the differential diagnosis of symptomatic intracranial masses, differential of low-grade and high-grade brain tumors, guidance of stereotactic biopsy of documented intracranial mass, monitoring response of treatment in patients with brain tumors, the assessment of cerebrovascular disease, bone scan for evaluation of low back pain, bone scan for lumbar metastases, and brain scan for fibromyalgia. March 1998.
97. Small intestinal bypass (jejunioileal bypass) for treatment of morbid obesity - (CPT 44131).
98. Sperm evaluation, Hamster penetration test (CPT-4 code 89329).
99. Spinoscopy. Use of a Spinoscope with skin markers to assess the function of the spine. CPT codes 95999 and 97799 have been used. August 1996.
100. Stem Cell Assay, Differential Staining Cytotoxicity (Disc) Assay and Thymidine Incorporation Assay. Laboratory procedures to predict the type and dose of cancer chemotherapy drugs to be used, based on in vitro analysis of their effects on cancer cells taken from an individual. The efficacy of these tests is not established by scientific data and does not reflect standard laboratory procedures provided in the United States. July 1996.
101. Stereotactic Cingulotomy. August 1996.

- 102. Sublingual immunotherapy. March 1997.
- 103. Synaptic 2000 for acute and chronic pain. June 1998.
- 104. Test of Variable of Attention (TOVA®) for diagnosing Attention Deficit Hyperactivity disorder and titrating pharmacotherapy levels. September 1997.
- 105. Testosterone pellet implants in the treatment of females. July 1996.
- 106. Therapeutic Apheresis/Plasmapheresis/Leukopheresis for the treatment of desmoplastic small round-cell tumor. June 1997.
- 107. Thermography.
- 108. Tinnitus Masker.
- 109. Topical Application of Oxygen. The clinical efficacy of oxygen by topical application has not been established and is considered unproven. August 1996.
- 110. Topographic brain mapping (TBM) procedure. "Brain mapping" performed from the surface of the scalp rather than from the surface of the brain or from deeper structures in the brain using indwelling electrodes. February 1997.
- 111. Transcatheter hepatic arterial embolization for the treatment of cancers that have metastasized to the liver, unresectable hepatocellular carcinoma and resectable hepatocellular carcinoma. June 1997.
- 112. Transcervical block silicone plug. June 1996.
- 113. Transdermal nicotine therapy used to treat ulcerative colitis. September 1997.
- 114. Transfer factor (TF). This is a dialyzable leukocyte extract (DLE) used to transfer delayed hypersensitivity from an immune to a nonimmune subject and is considered unproven. December 1989.
- 115. Transjugular Intrahepatic Portosystemic Shunt (TIPS) as initial therapy for acute or recurrent esophageal variceal bleeding, as treatment of refractory ascites, Budd-Chiari syndrome, hepatorenal syndrome, gastric variceal bleeding and preoperative portal decompression to facilitate liver transplantation. July 1997.
- 116. Transmyocardial laser revascularization for ischemic heart disease. October 1996.
- 117. Transurethral needle ablation (TUNA) of the prostate. October 1997.
- 118. Ultrafast CT to predict asymptomatic heart disease. October 1996.
- 119. Vertebral axial decompression for relieving low-back pain associated with herniated disc or degenerative disc disease of the lumbar vertebrae. October 1994.

120. Vestibular rehabilitation therapy used to treat benign paroxysmal positional vertigo. February 1997.

121. Videofluoroscopy evaluation in speech pathology.

122. Whole body hyperthermia in the treatment of cancer. Hyperthermia for recurrent breast cancer. July 1996.

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